UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
	)	Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	Subcategory No. 06-11337-PBS
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc., v. Boehringer Ingelheim Corp., et al., Civil Action No. 07-10248-PBS; and	)	Hon. Patti B. Saris
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey L.P., et al., C.A. No. 05-11084.	)	

UNITED STATES' REPLY MEMORANDUM IN FURTHER SUPPORT OF UNITED STATES' MOTION TO CONSOLIDATE CASES FOR TRIAL

In opposing the United States' motion for consolidation, defendants claim that a consolidated trial would be too long and complex, that consolidation would be unduly prejudicial, and that the government's "combined impact theory" with respect to ipratropium bromide has no merit. These arguments fail. Further, defendants ignore the fact that separate trials will require substantial duplication of effort and cause inconvenience to the Court and government witnesses. In addition, with regard to the drug responsible for the vast majority of damages in both cases, consolidation avoids the risk of inconsistent results from having two juries separately rule on the same question: what was the impact of both companies' price reporting on Medicare spending for ipratropium bromide?

A. Defendants Dramatically Overstate the Distinctions Between the Cases Against Dey and Roxane

Despite going to great lengths to emphasize the differences between the cases against them, neither Dey nor Roxane disputes that the government witnesses likely to be called at trial, as well as the documentary evidence relating to the Medicare and Medicaid programs, will be largely the same in both cases. Each case includes essentially identical evidence of how Medicare reimbursed for drugs (and for inhalation therapy drugs in particular), including similar evidence relating to the operation of the Durable Medical Equipment Regional Carriers ("DMERCs") responsible for setting reimbursement amounts. Likewise, the cases involve essentially identical evidence relating to Medicaid, including evidence of the various states' reimbursement formulae.[1] Defendants have offered no reason to suggest that the presentation of this evidence will differ materially from one case to the other.[2]

Instead, the differences highlighted by Dey and Roxane almost exclusively relate to distinctions between the companies themselves, such as Roxane's sale of "branded generic" products, and the companies' different practices with regard to reporting WACs. In particular, defendants emphasize that there are nine drugs with a range of therapeutic uses at issue in the Roxane case, while the three drugs at issue in the Dey case are all used for inhalation therapy. Viewed against the similarity of the United States' allegations against each company, such distinctions are of little significance. The heart of the United States' case against both

[1]The pattern of discovery certainly suggests that the overlap between the cases is greater than any differences. At least 100 federal and state witnesses have been deposed to date in the United States/Ven-A-Care litigation, compared to approximately 50 Dey and Roxane employees.

[2]While defendants note that the damages period in the Dey case begins in 1992, compared to 1996 in the Roxane case, they fail to explain why this will be confusing to a jury. Dey Opposition, p. 10.

companies is that they knowingly reported false AWPs. The United States will offer evidence that the reported AWPs for each of the Subject Drugs bore no relationship to actual sales prices. Proof that defendants acted knowingly will be presented through evidence of how defendants marketed and set prices for certain of the Subject Drugs. For example, evidence that Dey acted knowingly when reporting false prices for ipratropium bromide includes evidence of Dey's purpose in setting AWPs at ten percent below the brand AWP for albuterol sulfate and cromolyn sodium, and Dey's continuation of that practice for ipratropium bromide. *See* United States' Local Rule 56.1 Statement of Undisputed Material Facts as to Dey, ¶¶ 81- 84, 89-90, 98-100, 136-142.

Thus, while there obviously will be differences in the evidence presented as to each defendant, the jury will not be required to hear twelve different presentations relating to the marketing history of every drug and, contrary to defendants' suggestion, there is no reason to think that the evidence will vary significantly depending on the type of drug at issue. Furthermore, evidence as to each defendant's conduct likely will be presented sequentially, allowing the jury to distinguish easily between the evidence against each company.

B. Defendants Fail to Show That They Will Be Prejudiced By Consolidation

Defendants have fallen far short of showing the "demonstrable prejudice" necessary to defeat a motion for consolidation. *See Seguro de. Servicio de Salud v. McAuto Sys.*, 878 F.2d 5, 8 (1st Cir. 1989). The primary risk of prejudice identified by defendants – that the jury will confuse the evidence against them – is curable by presenting the evidence against each defendant sequentially, and giving cautionary jury instructions. *See Arnold v. Eastern Air Lines*, 681 F.2d 186, 192-93 (4th Cir. 1982) (consolidating cases for trial, and noting that the "obvious" "risks of

prejudice and possible confusion" were controllable through cautionary instructions). Other potential "risks" of prejudice identified by defendants amount to little more than pointing there are inevitable distinctions between any two defendants' conduct, but neither Dey nor Roxane demonstrate how or why such distinctions are prejudicial here. For example, it is far from clear how a comparison between the companies' different practices for reporting WACs would be prejudicial, and if it was, whether the comparison would prejudice one of the defendants or the United States. Such speculative risks are insufficient reasons to deny consolidation, particularly where the benefits to judicial economy from consolidation are as great as they are here. *See In re Bear Stearns Co. Inc. Securities, Derivative, and Employee Retirement Income Security Act Litig.*, 2009 WL 50132, * 7 (S.D.N.Y. 2009) (refusing to deny consolidation of cases based on speculative concerns about prejudice).

In the cases relied on by defendants, the court generally denied motions to consolidate because the proof involved in the respective cases was wholly distinct, and/or the motion sought to consolidate several different cases. For example, *Henderson v. AT&T Corp.*, 918 F.Supp. 1059, 1063-64 (S.D. Tex. 1996), involved a request to consolidate five separate claims for employment discrimination. The Court denied the request to consolidate on grounds that the plaintiffs' claims were "highly individualized," that the claims were for race *and* gender discrimination, and that plaintiffs "worked on separate teams, in separate offices calling on different customers." *Id.* In addition, the Court specifically noted that in the parties' initial Rule 26 disclosures, "very few" witnesses appeared on all the disclosure lists. *Id.* Here, as noted above and in the United States' opening memorandum, there is extensive overlap in the likely trial witnesses in the Dey and Roxane cases. United States' Memorandum in Support of Motion

to Consolidate, 9-10 (noting the extensive overlap between Roxane and Dey's Initial Disclosures). In addition, defendants fail to mention that although *Henderson* denied the request to consolidate the five cases for trial, the Court did permit two of the plaintiffs to proceed jointly, despite factual differences in their claims. *Henderson*, 918 F.Supp. at 1064; *see also Puricelli v. CNA Ins. Co.*, 185 F.R.D. 139, 143 (N.D. N.Y. 1999) (distinguishing *Henderson*, and permitting consolidation of two cases arising under the ADEA on the ground that "any prejudice or confusion can be remedied by a carefully drafted jury instruction"); *Smith v. Northeastern Ill. Univ.*, 2002 WL 377725, * 5 (N.D. Ill. 2002) (same).

The United States' claims against Dey and Roxane rest on broadly similar legal theories and factual allegations, and fall squarely within the type of cases typically consolidated for trial despite minor evidentiary differences in each case. *See, e.g.*, *Sofran v. LaBranche & Co.*, 220 F.R.D. 398, 401 (S.D.N.Y. 2004) (consolidating class actions securities fraud cases because each action asserted similar and overlapping claims); *Microstrategy Inc. Securities Litig.*, 110 F.Supp.2d 427, 431 (E.D. Va. 2000) (consolidating securities fraud suits for trial, and noting that "the existence of slight differences in class periods, parties, or damages among the suits does not necessarily defeat consolidation where the essential claims and factual allegations are similar"); *Bowman v. Legato Sys., Inc.*, 195 F.R.D. 655, 656-57 (N.D. Cal. 2000). Furthermore, a substantial part of the government's case against defendants is grounded on principles of joint and several liability arising out of an indivisible injury caused by the combined impact of defendants' wrongful conduct. Trying claims against joint tortfeasors is customarily done in a consolidated trial, regardless of differences in the specific conduct of the tortfeasors.

C. The United States Is Entitled to Present Evidence of Both Companies' Pricing Conduct for Ipratropium Bromide

Although Dey and Roxane claim that the United States' "combined impact theory" is "unsupported" and "unprincipled," neither company disputes the essential fact that their reported AWPs had a joint impact on Medicare spending by combining to increase the median AWP for ipratropium bromide. Instead, defendants assert that the United States cannot recover the full amount of damages actually caused by their respective price reporting because each company's conduct was an intervening force negating causation as to the other, and because they did not conspire to defraud Medicare. Neither argument withstands scrutiny.

Causation under the False Claims Act generally involves application of common-law tort principles. *See United States ex rel. Franklin v. Parke-Davis*, 2003 WL 22048255, * 4 (D. Mass. 2003). Such principles have been summarized in the First Circuit as follows:

> [T]here are two questions that must be answered to determine if a defendant's conduct "caused" a plaintiff's injury. The first question is whether there was in fact some causal relationship between the conduct and the outcome. The Restatement expresses this test as whether the defendant's conduct was a "substantial factor" in producing the harm. The second question is whether the circumstances and causal relationship are such that the law will impose liability on the defendant. Sometimes this is expressed as a foreseeability test.

Rodriguez-Cirilo v. Garcia, 115 F.3d 50, 54 (1st Cir. 1997) (citing Restatement (Second) of Torts, § 431 (1965); *see also Clement v. U.S.*, 980 F.2d 48, 54 (1st Cir. 1992) (citing the Restatement and noting that a defendant causes an injury when his conduct "creates a risk that

might reasonably be expected to result in such injury or damage, even though the exact nature of the injury or damage need not, itself, be foreseeable.").[3]

Here, the United States expects to prove that Dey and Roxane each reported inflated AWPs for ipratropium bromide. As the applicable regulation provided that Medicare reimbursed for multiple-source drugs at 95% of the median of generic AWPs, *see* 42 C.F.R. 405.517(c) (1998), it was certainly foreseeable to defendants that reporting inflated AWPs would create a risk that the median AWP would be increased, thereby causing Medicare to pay more in reimbursement than it otherwise would have. This, by itself, is sufficient to subject defendants to liability for the full injury to Medicare. *Clement*, 980 F.2d at 54; *see also* Restatement (Second) of Torts, § 435(2) (1965) (If an "actor's conduct is a substantial factor in bringing about harm to another, the fact that the actor neither foresaw nor should have foreseen the extent of the harm or the manner in which it occurred does not prevent him from being liable.")

In addition, the United States expects to introduce evidence that Dey and Roxane both knew or reasonably should have known that each other's AWPs were inflated and, therefore, that the injury to Medicare caused by their inflated AWPs might be exacerbated by the conduct of the other. Specifically, Dey set its published AWPs for ipratropium bromide in reference to Roxane's AWPs, which Dey knew were set at ten percent below the brand AWP. Henderson Exhibit 69, attached hereto as Exhibit 1; *see also* United States' Local Rule 56.1 Statement of Undisputed Material Facts as to Dey (MD #6296, Sub. # 302), ¶¶ 136-42. Likewise, Roxane

[3] Dey attempts to distinguish these provisions of the Restatement on the ground that they relate to negligence, and this is not a negligence case. Dey Opposition, 16. But the comments to § 431 show that it applies to intentional (as well as negligent) conduct: "Although the rules in this Section are stated in terms of the actor's negligent conduct, they are equally applicable where the conduct is intended to cause harm." Restatement (Second) of Torts, § 431 (1965), comment e.

monitored Dey's AWPs and sales prices for ipratropium bromide, as evidenced by an October 1998 email sent by Roxane's Assistant Director of Multi-source marketing comparing both companies' prices. Fauci Exhibit 55, attached hereto as Exhibit 2.

Defendants' claim that they did not conspire or act in concert to defraud Medicare is also a red herring. Under the common law, multiple defendants are liable for a common injury caused by their independent tortious conduct, irrespective of whether defendants acted in concert or independently. *See, e.g., Shepard v. General Motors Corp.*, 423 F.2d 406, 408 n.2 (1st Cir. 1970) ("The general rule is that where two independent, negligent acts combine to produce a single, indivisible injury, the actors are jointly and severally liable"); *Hawley v. American Eagle Sailing, Inc.*, 2007 WL 3012133, * 1 (M.D. Fla. 2007) ("Joint and several liability among multiple tortfeasors exists when the tortfeasors, acting in concert *or through independent acts*, produce a single injury.") (emphasis added); *Agere Systems, Inc. v. Advanced Environmental Technology Corp.*, 552 F. Supp. 2d 515, 520 (E. D. Pa. 2008).

D. Roxane's Proposal of Empaneling Separate Juries Should Be Rejected

Given the evidence that Dey and Roxane's conduct combined to harm the Medicare program by inflating the median AWP, the United States is entitled to present evidence of both companies' conduct with regard to ipratropium bromide to a single jury. As in any case against joint tortfeasors, having this evidence heard separately runs a high risk that the juries would reach inconsistent verdicts on whether defendants' wrongful conduct jointly harmed Medicare, and whether and how damages should be apportioned. This factor weighs heavily in favor of consolidation. *See, e.g., International Paving Sys. v. Van Tulco, Inc.*, 806 F.Supp. 17, 22 (E.D. N.Y. 1992). Furthermore, because each company's price reporting conduct was part of a pattern

and practice involving other Subject Drugs marketed by the same company, any attempt to separate out conduct relevant only to the joint and several liability claims would be unworkable.

The United States does not dispute that any trial of these cases will likely be lengthy and complex. To mitigate this, the Court could order that the trial proceed in two phases before a single jury. The first phase would encompass the United States' Medicare claims against Dey and Roxane. Following the jury's verdict, a possible second phase could encompass the Medicaid claims. There are several advantages to sequencing the case in this manner. First, the Medicare case is comparatively simpler, in that it involves a single federal agency and one reimbursement formula. In addition, the Medicare case involves substantially fewer drugs and a shorter time period, as the United States has only calculated Medicare damages through 2003, for ipratropium bromide (as to Dey and Roxane) and albuterol sulfate (as to Dey only).

In addition, proceeding in this manner will serve the interests of judicial economy because the Medicaid phase of the trial might prove unnecessary. Irrespective of outcome, the jury's verdict on the Medicare claims will color each party's view of the potential for resolving the Medicaid cases without trial. More important, given the substantial damages calculated by the government on the Medicare claims, even before calculating penalties, a full verdict in favor of the United States on these claims would, as a practical matter, provide appreciable incentive to resolve the remaining claims without further proceedings.

TONY WEST
ASSISTANT ATTORNEY GENERAL

Laurie A. Oberembt
Joyce R. Branda
Daniel R. Anderson
Laurie A. Oberembt
Civil Division
Commercial Litigation Branch
P. O. Box 261
Ben Franklin Station
Washington, D.C. 20044
(202) 514-3345

CARMEN M. ORTIZ
UNITED STATES ATTORNEY

By: /s/ James J. Fauci
George B. Henderson, II
Barbara Healy Smith
James J. Fauci
Assistant U.S. Attorneys
United States Courthouse
1 Courthouse Way, Suite 9200
Boston, MA 02210
(617) 748-3272

FOR THE RELATOR,

James J. Breen
Allison Warren Simon
The Breen Law Firm, P.A.
5755 Northpoint Parkway, Suite 260
Alpharetta, GA 30022
Tel. (770) 740-000
fax: (954) 499-1173

Gary Azorsky, Esq.
Susan Schneider Thomas, Esq.
Roslyn Pollack, Esq.
Berger & Montague, P.C.
1622 Locust St.
Philadelphia, PA 19103
(215) 875-3090

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above document and accompanying exhibits to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ James J. Fauci
James J. Fauci
Assistant U.S. Attorney

Dated: November 16, 2009

Exhibit 1

Exhibit 69

United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., et al.,
Civil Action No. 05-11084-PBS

Exhibit to the July 24, 2009, Declaration of George B. Henderson, II
In Support of Plaintiffs' Motion For Partial Summary Judgment
and In Opposition To Dey's Motion For Partial Summary Judgment

Ipratropium Bromide Inhalation Solution 0.02%

Dey Laboratories Marketing Plan

Target Launch Date: October 15, 1996

Prepared June 28, 1996 by: Todd Galles
Eve Gmeiner
Debra Bronstein

Table of Contents

I. OVERVIEW

Chronic Obstructive Pulmonary Disease (COPD) is a term used to describe a number of obstructive airway diseases. Typically COPD encompasses both chronic bronchitis and emphysema, with one disease being more prevalent than the other. Chronic bronchitis patients suffer from inflamed epithelial walls and cough up excessive sputum. Emphysema patients suffer from abnormally enlarged air sacs and therefore have a difficult time expelling air.

Approximately 12-15 million people suffer from COPD. It is most prevalent in 65-84 year olds, and affects both men and women about equally. It is currently the fourth leading cause of death in the U.S.

COPD is most typically attributed to smoking, and is an irreversible disease. However, progression of the disease can be stayed by smoking cessation and medication usage. Anticholinergics (ipratropium bromide) are considered first line therapy and beta agonists (albuterol & metaproterenol) second line. Ipratropium is currently the only anticholinergic sold in the U.S.

Ipratropium bromide is classified as a bronchodilator although it technically does not dilate the muscles. It is classified as such because it prevents the constriction of the bronchial smooth muscle by competing with acetylcholine for receptor sites on the smooth muscle (acetylcholine causes the smooth muscle to constrict). Ipratropium bromide works primarily on the large bronchioles whereas beta agonists work on the smaller bronchioles.

Ipratropium bromide adds a critical product to DEY's respiratory line, as it offers DEY the opportunity to enter the COPD market. The product displays strong growth potential, as a whole generation of smokers will be entering the critical age for COPD in the next ten years, and because ipratropium is increasingly being used to treat asthma. As the chart on the following page indicates, ipratropium has gained market share in a growing respiratory market.

II. SITUATION ANALYSIS

A. IPRATROPIUM AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Ipratropium Bromide is "indicated as a bronchodilator for maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema."[1]

B. COPD: THE DISEASE

COPD differs from asthma in a number of ways as the table below illustrates:

	Asthma	COPD
Cause of airway obstruction	Release of histamines	Bronchomotor tone
Airways primarily affected	Small bronchioles	Large bronchioles
Airway reversibility	Reversible	Minimal to none
Bronchoconstriction	Episodic	Chronic

1. Treatment Protocol

According to published protocol [2], treatment of COPD follows this sequence:

- #1 Smoking cessation
- #2 Add treatment with bronchodilators
  - -First ipratropium bromide alone
  - -Add beta agonist (albuterol, metaproterenol) if not responding to I.B.
- #3 Add theophylline
  - -For those with nocturnal symptoms or unrelieved from combo from step #2
- #4 Corticosteroids (primarily inhaled)
  - -For those still having problems in spite of treatment steps #1-3

II. SITUATION ANALYSIS
B. COPD: THE DISEASE (continued)

Dosing regimens for bronchodilators are as follows:

Ipratropium:	0.02% (one unit-dose vial) 3-4 times per day by oral nebulization, with doses 6-8 hours apart
Albuterol:	0.083% (one unit-dose vial) 3-4 times per day by oral nebulization

In some cases, it may be beneficial to combine the beta agonist and anticholinergic therapies as a "cocktail" for nebulization. Typically one unit-dose vial of ipratropium bromide (500 mcg) is mixed with 0.5 mL of albuterol concentrate in a nebulizer.

The combination of both drugs has been shown to increase the area under the FEV_1 curve by 52% (as measured on day 85 of the combined therapy).[3] However, the "combination of *Atrovent* and beta agonists has not been shown to be more effective than either agent alone in reversing the bronchospasm associated with acute COPD exacerbation."[4]

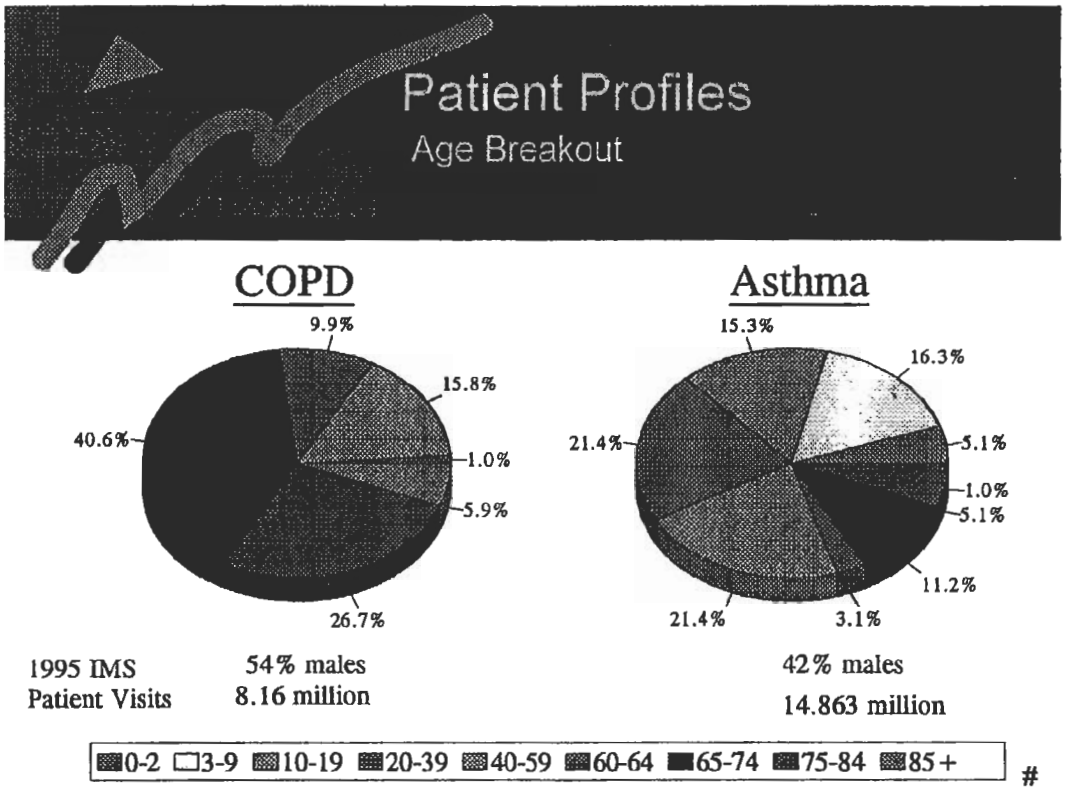
Despite treatment protocol, audits indicate the following usage frequency for medications and COPD:

Beta Agonists - 37%
Xanthines - 30%
Ipratropium Bromide - 23%
Bronchial steroids - 17%
Oral corticosteroids -13%
Beta Agonist Nebulizer Solutions - 12%
Source: NDTI Diagnosis

II. SITUATION ANALYSIS
B. COPD: THE DISEASE (continued)

2. COPD Demographics

COPD affects about 5% of the U.S. population (12-15 million people) and is the fourth leading cause of death in the U.S.[5] The costs associated with the disease in 1990 were estimated at $12 billion dollars.[6] The number of COPD cases is expected to increase through the end of the century, as baby boomers are aging and as an entire generation of smokers enters the critical ages associated with COPD: 65-84. The disease is much more prevalent in men than is asthma.



COPD patients see a doctor an average of 5-6 times per year. When the disease is diagnosed, 53% of the time it is concomitantly diagnosed. Most frequent concomitant diagnoses include hypertension, congestive heart failure, diabetes, asthma and bronchitis, in descending order. Physicians diagnosing COPD include IMs (32%), PUDs (23%) and FPs (18%).

II. SITUATION ANALYSIS

C. IPRATROPIUM BROMIDE USAGE

The most common dosing for ipratropium as indicated in IMS audits is:

Aerosol: "2 4x/day"
Solution: "4 per day"

Ipratropium, however, is rarely used alone in treating COPD. According to Boehringer Ingelheim, 60% of COPD patients receiving *Atrovent* are co-prescribed a beta agonist like albuterol. Boehringer noted that 70% of beta agonist use is prescribed on a regular basis, and 81% of patients using *Atrovent* are using it on a continuous basis.

The most frequently prescribed concomitant medications for use with both aerosol and solution forms of ipratropium are:

Beta Agonists (48%)
Bronchial Corticosteroids (MDIs) (27%)
Xanthines (theophylline) (19%)
Oral Corticosteroids (16%)
Beta Agonist Nebulizer Solutions (15%)

Usage data collected from home care pharmacies support the usage patterns indicated above, as this user group reported a usage ratio of 1 ipratropium vial to 3 albuterol unit-dose vials.[7]

In analyzing what diseases ipratropium is being used to treat, 70% of all ipratropium usage is associated with treating COPD. 19% of ipratropium usage is associated with treating asthma, even though this is currently an off-label indication. The use of ipratropium in treating asthma is growing, however. Most recently, at the American Academy of Pediatrics spring session, a presentation was made in which ipratropium was promoted for use with asthmatic children who do not respond to either beta-agonists or corticosteroids.[8]

II. SITUATION ANALYSIS

C. IPRATROPIUM BROMIDE USAGE (continued)

17% of all doctor visits associated with the use of *Atrovent* in 1995 were new visits, up slightly from 15% in 1994. 68% of scripts for *Atrovent* are written by IMs, FPs and PUDs.

Physician Specialty	% of all ATROVENT scripts filled which were written by this specialty	Average # of ATROVENT scripts written per year
Internal Medicine	28%	23
Family Practice	20%	13
Pulmonary Disease	19.6%	282

PUDs are more than ten times as productive in writing scripts for *Atrovent* than other physician specialties.

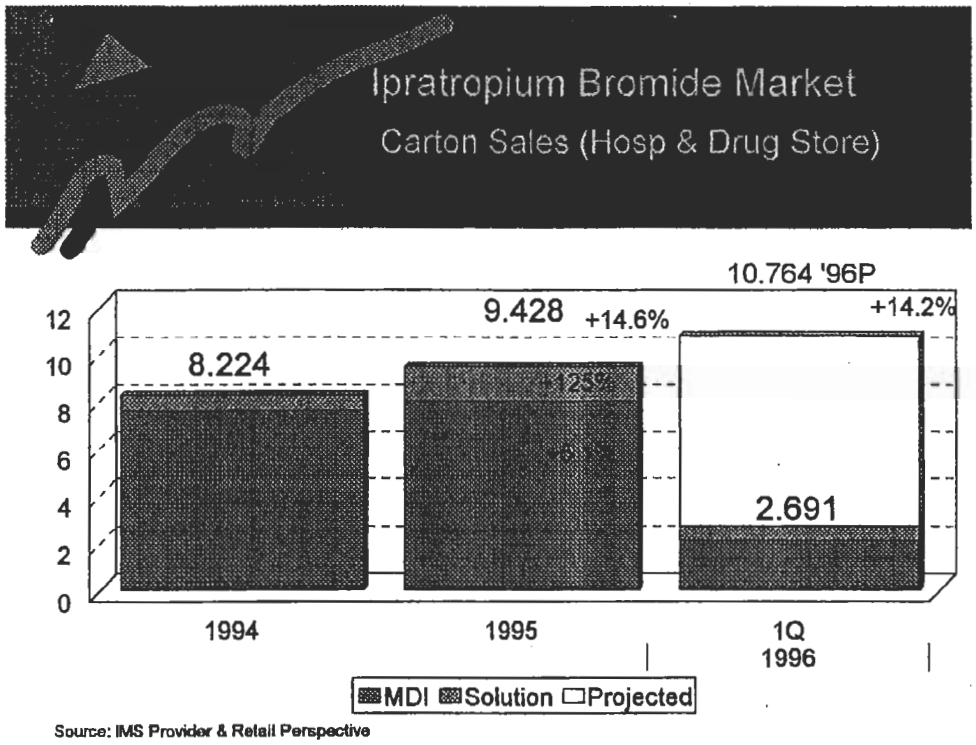
D. MARKET OUTLOOK

According to Find/SVP, COPD patients will be a primary driving force in the dollar growth of the respiratory market through the end of the century, primarily because the disease is chronic and incurable. The company estimates use of anticholinergics will grow at a compound annual growth rate of 6.7% through 1999, growing from $131 million in sales in 1994 to $163 million in 1999.

Sales of ipratropium bromide (both MDI and solution) increased 14.6% in 1995 in carton volume.[9] Using 1Q96 sales as a baseline to project 1996 sales, carton sales are projected to increase another 14.2% (see chart next page).

II. SITUATION ANALYSIS

D. MARKET OUTLOOK (continued)



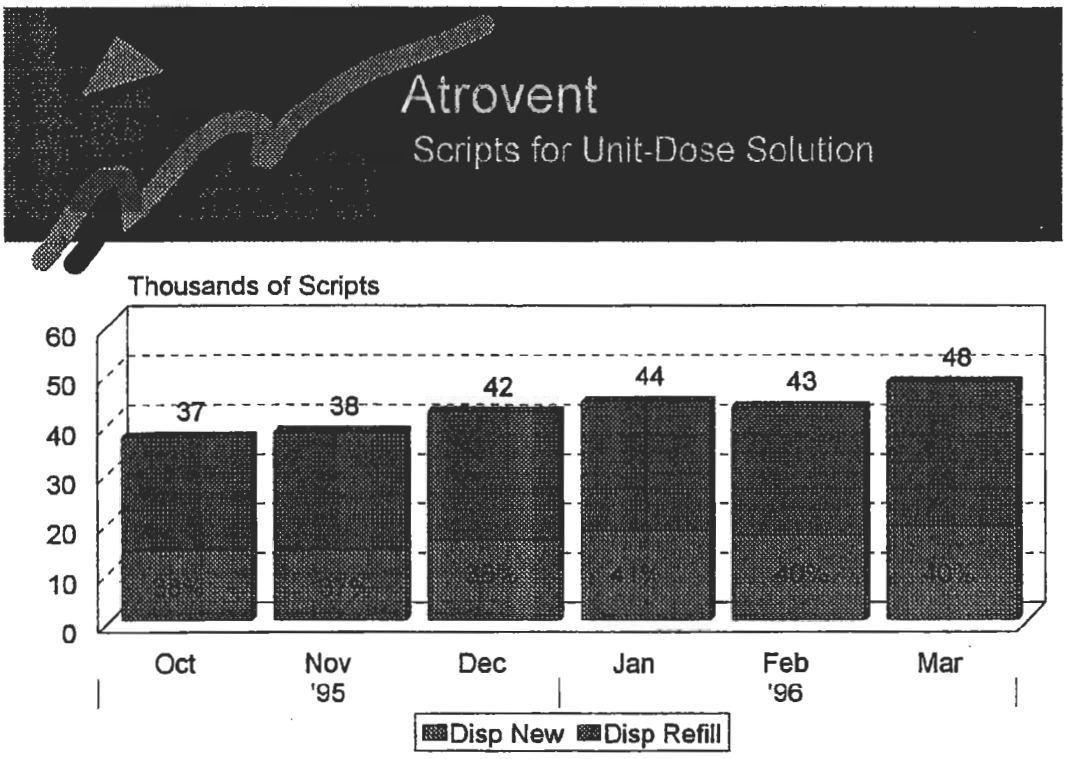
Source: IMS Provider & Retail Perspective

Unit-dose ipratropium grew 125% in carton volume in 1995, taking into account that the solution form of *Atrovent* was introduced in April 1994.

Sales of ipratropium solution have far out paced the growth in the overall unit-dose respiratory market (125% vs. 20% for unit-dose products overall). However, Boehringer Ingelheim suffered significant back order problems with the solution in 1995. The sales reps had promoted the product so well that doctors were writing scripts faster than Boehringer could manufacture the product. If the back order problem had not occurred, the percent increase in carton volume for ipratropium solution would have probably been even greater than 125%.

II. SITUATION ANALYSIS
D. MARKET OUTLOOK (continued)

Data on dispensed prescriptions reveals strong growth potential for this market, particularly in new prescription volume. Refill prescriptions account for nearly 60% of all product volume, as would be expected with a maintenance therapy product. The remaining 40% in new prescription volume, however, indicates the growth of new COPD cases and may reflect the growing use of *Atrovent* in asthma.



Source: NPA TCR 1995

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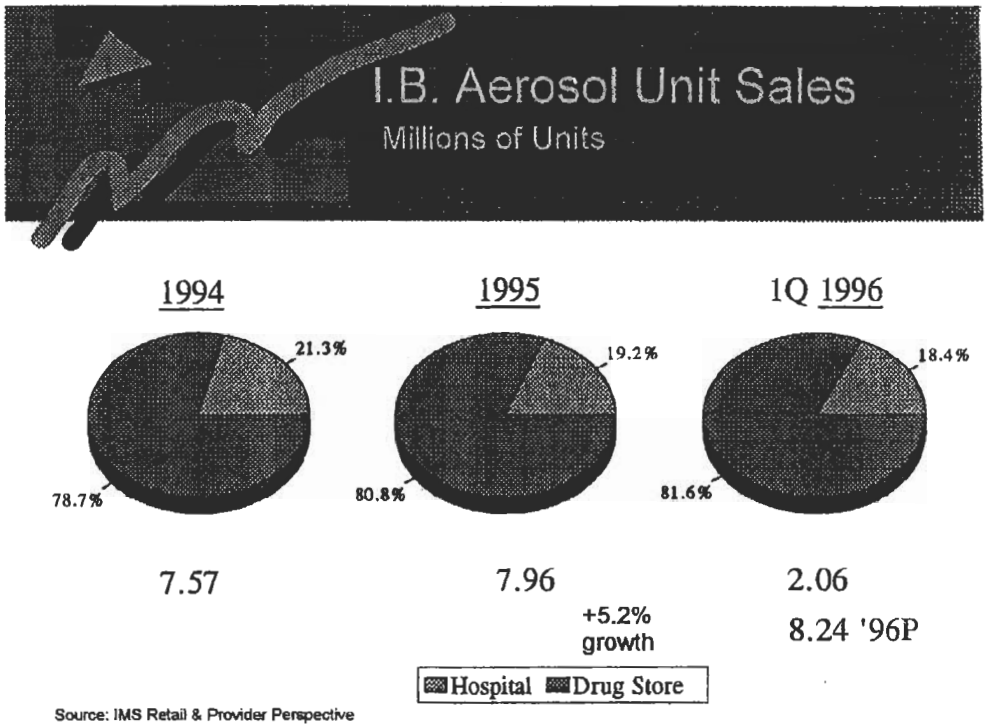
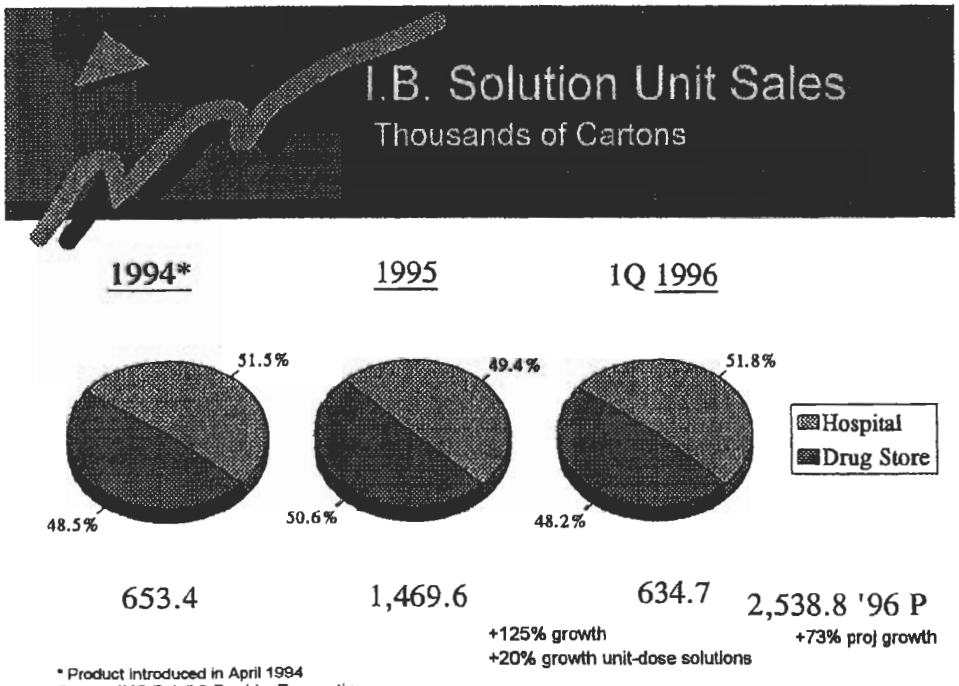
II. SITUATION ANALYSIS
D. MARKET OUTLOOK (continued)

Sales channels for ipratropium differ significantly between the MDI and the solution. 82% of ipratropium MDI sales move through drug stores.

This follows the general trend seen in the respiratory market where MDI sales are increasing as the predominant form for inhaled respiratory products.



Source: IMS Retail & Provider Perspective



Sales of ipratropium bromide solution, however, are split equally between drug stores and hospitals, as might be expected.

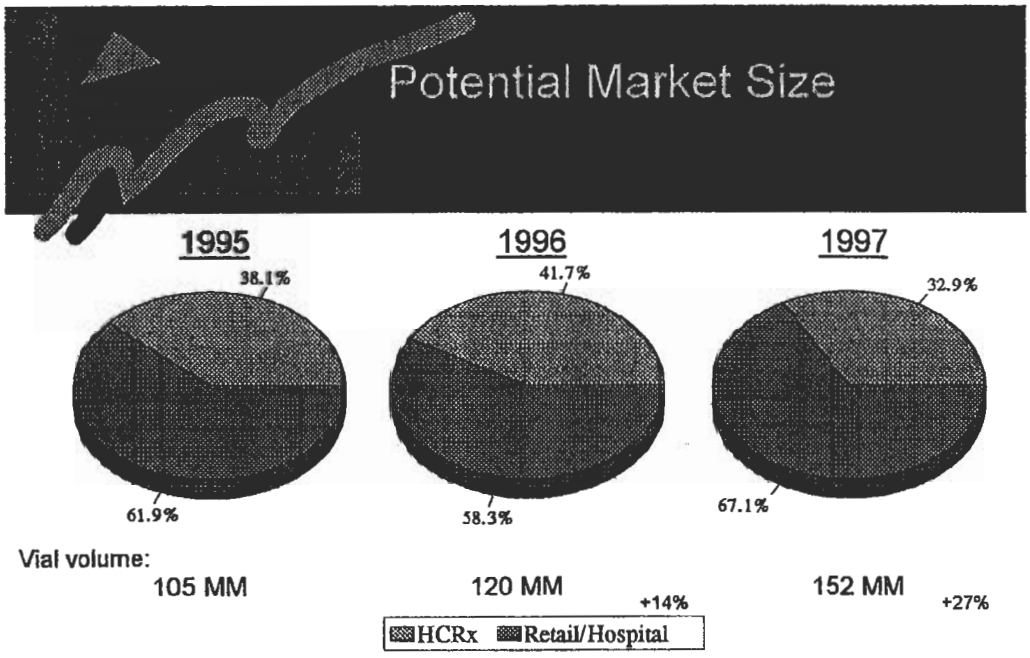
* Product introduced in April 1994
Source: IMS Retail & Provider Perspective

II. SITUATION ANALYSIS

D. MARKET OUTLOOK (continued)

The market potential for ipratropium solution is difficult to determine, as product sales to date do not reflect the significant back order problem Boehringer experienced with *Atrovent* solution in 1995. Although Boehringer is now supplying more product, there is still a fair amount of unmet demand from the doctors who were detailed on the solution and wrote prescriptions for it, but then learned that their patients could not fill their prescriptions due to back order problems. Although these doctors stopped writing prescriptions for *Atrovent* solution, as it becomes more readily available, they may start writing again. In fact, sales figures for first quarter, 1996, indicate this is already happening: (see previous chart) 1Q96 sales were about 20,000 cartons shy of ALL product sold from April-December 1994.

Thus, the market is projected to grow as follows:



Retail/Hospital includes estimates for RGDs and Mail Order
Source: IMS & Internal data

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II. SITUATION ANALYSIS

E. COMPETITORS

Currently two companies distribute ipratropium bromide solution: Boehringer Ingelheim distributes the branded product *Atrovent* and Roxane Laboratories, a subsidiary of Boehringer, distributes the generic equivalent. Both companies market unit-dose vials of the solution in cartons of 25s. No other carton configuration is available.

1. Boehringer Ingelheim

Boehringer Ingelheim Pharmaceuticals is the largest of all companies that form part of Boehringer Ingelheim Corporation, and is headquartered in Ridgefield, Connecticut. The Corporation is a subsidiary of Pharma-Investment Ltd. of Toronto, Canada. Boehringer Ingelheim Pharmaceuticals, Inc. is the principal licensee of Boehringer Ingelheim International GmbH of Germany.

Respiratory products account for 42% of all Boehringer Pharmaceutical sales. *Atrovent* is Boehringer's #1 selling product. Sales of *Atrovent* are primarily in the MDI format. Most recently, Boehringer sales representatives have started to focus sales efforts on their newest *Atrovent* product: nasal sprays (0.3% and 0.6%).

Other respiratory products offered by the company include *Alupent* (metaproterenol) and *Respbid* (theophylline). *Combivent* (albuterol and ipratropium MDI) is awaiting final approval for marketing from the FDA.

Boehringer Pharmaceuticals has 400 sales reps, with 65 hospital reps, one per district. The company also has a small managed care sales force of about 10 reps. In general, the Boehringer sales force is highly trained and is a veteran force with very little turnover. Boehringer Pharmaceuticals has warehouse and distribution facilities in Brookfield, Connecticut and in Reno, Nevada.

The company spent roughly $13 million in 1994 and 1995 on detailing *Atrovent* (both MDI and solution). Sales calls with samples increased from 76% of all detail calls in 1994 to 85% in 1995. In general, Boehringer reps call on IMs, FPs, PUDs and Allergists when selling their respiratory products.

II. SITUATION ANALYSIS
E. COMPETITORS (continued)

1. Boehringer Ingelheim (continued)

Boehringer has approached the home care market with three year contracts for the *Atrovent* solution, which has been met with mixed success. Some home care pharmacies have signed a one year contract for *Atrovent* instead of the three year agreement.

Boehringer decided to introduce the generic version of *Atrovent* through its own subsidiary, Roxane, three months prior to the expiration of the patent on September 30, 1996. Currently, Boehringer appears to be matching Roxane pricing on contract.

Boehringer *Atrovent* messages initially focused on combination therapy (*Atrovent* and albuterol) for COPD and the increased benefits in FEV_1 (see ad in Appendix). Current ads position *Atrovent* as maintenance therapy for COPD patients, emphasizing its unique mode of action in blocking bronchoconstriction and working on large, central airways (see ad in Appendix).

To date, Boehringer has focused distribution of *Atrovent* solution through wholesalers and non-warehousing chains (see chart p.18). Boehringer uses this approach for several reasons:

1) Boehringer believes in creating the demand through the physician, forcing the pharmacist to stock the product through the wholesaler
2) As a patented product, they do not wish to pay rebates and do not have a need for RGDs
3) Boehringer does not have a particularly strong direct shipping system

II. SITUATION ANALYSIS
E. COMPETITORS (continued)

2. Roxane

Roxane Laboratories is a subsidiary of Boehringer Ingelheim Corporation, and is located in Columbus, Ohio. The company promotes itself as a "pioneer" in the development of unit-dose packaging for hospitals and nursing homes. Roxane is considered a niche generic, selling products for which there are few competitors.

The company manufactures 450 line items in tablet, capsule, suppository and liquid forms with a specialization in oncology products. Respiratory products Roxane manufactures include ipratropium bromide (both the brand and generic), prednisone (tablets and syrup), normal saline and theophylline (solution). Roxane used to carry both isoetharine and metaproterenol unit-dose vials as well. Other products manufactured by Roxane include *Roxanol* (morphine), *Oramorph SR* (morphine) and *Marinol* (anti-nauseant).

Roxane has 75 sales reps and four NAMs. NAMs call on chains and managed care accounts. The sales force does not have a reputation for being aggressive or particularly strong, and has a fair amount of turnover. Representatives focus primarily on hospitals, clinics and hospices. Recently, Roxane has started selling to home care pharmacies.

Roxane has a very strong relationship with wholesalers, having built a number of rebate programs which offer quarterly rebates (up to 5%) and royalty bonuses, or annual rebates, which can run from 5-7%. The relationship is further strengthened by multi-product deals they offer wholesalers which include their oncology products. Roxane is not particularly strong in retail, and does not sell to Retail Generic Distributors unless they are members of NWDA, thus most RGDs will be excluded. This presents an opportunity for DEY.

II. SITUATION ANALYSIS
E. COMPETITORS (continued)

Roxane introduced the generic version of *Atrovent* June 1, 1996. The company has always manufactured the solution for Boehringer, and shut down their unit-dose metaproterenol lines in 1995 to increase production capacity for ipratropium.

Currently, Roxane has been selling ipratropium bromide solution through all the normal channels: wholesalers (independents, hospitals) and some warehousing chains. They have also targeted home care pharmacies with three-year exclusive contracts.

Promotion of ipratropium bromide centers around being "the first generic" ipratropium, offered at "substantial savings" (see Appendix).

III. TARGET MARKETS

Based on ipratropium usage trends and on demographic data as described above, the primary target markets for this product, in descending order, are Home Health Care, Mail Order, Hospitals, and Retail Pharmacies.

Market:	**Home Health Care**
Supplied by:	DEY direct; Wholesalers
Potential vial volume 1996:	50 million

HHC encompasses home care pharmacies.

67% of COPD patients (8-10 million people) are between the ages of 65-84 and are ambulatory, requiring continuous treatment that is often given in the home. Medicare will be a driving factor in this population segment, and as HHC works in conjunction with DME dealers and Medicare reimbursement, this will be a strong channel for ipratropium solution. In addition, market research indicated usage of ipratropium solution in this sector is high (1:3 ipratropium to albuterol)[10], and indeed HHC companies compound a fair amount of ipratropium bromide. IMS data indicates that new prescriptions for *Atrovent* solution in the first quarter of 1996 are up 250% over the same period last year. Although the full potential of ipratropium in this market sector is not known, it is an untapped market with significant potential for DEY.

The importance of this sector in reaching the target population, combined with DEY's strength in this sector make it the primary target market for DEY's ipratropium bromide solution.

III. TARGET MARKETS (Continued)

Market:	**Mail Order**
Supplied by:	DEY direct
Mkt. Potential vial volume 1996:	NEED THIS # FROM RFM

IMS data tracking Mail Order activity (IMS captures 90% of the mail order market) indicates new prescriptions for *Atrovent* solution in 1Q96 are up 50% over 4Q95. In addition, 20% of all prescriptions written for *Atrovent* solution in MO were for a 7 month supply of product (35 cartons of 25). The second most frequently prescribed volume in MO was for a 2 month supply, accounting for 7.4% of all prescriptions written for *Atrovent* solution in this sector.

Several factors make this market segment the next highest priority for DEY in promoting ipratropium:

1) COPD patients will most likely be on medication for life, including ipratropium. These patients typically prefer to purchase several months' supply of medication at a time, and frequently use Mail Order pharmacies to save on cost. Establishing a leadership position in this sector is therefore very important.
2) Mail Order is increasingly playing a more important role in filling prescriptions in the retail sector. DEY has a unique 60-vial package which is better suited to meet the needs of the mail order business.
3) With the majority of COPD patients (67%) between 65 and 84 they are likely to be members of AARP. AARP has a strong (and growing) mail order franchise
4) Neither Roxane nor Boehringer is not targetting this sector.

DEY is building strong relationships with customers in this segment, and has a unique opportunity to take a leadership position here.

III. TARGET MARKETS (Continued)

Market:	**Hospitals** (acute and alt. care)
Supplied by:	DEY direct; Wholesalers
Mkt. Potential vial volume 1996:	28 million

COPD patients are often diagnosed with many other illnesses at the time they are diagnosed with COPD. As such, many are hospitalized, and despite managed care's impact in reducing the number of days a patient stays in the hospital, this market is an important segment for ipratropium solution sales. As seen previously, roughly 50% of ipratropium bromide solution product is found in hospitals. Here, DEY is the market share leader in unit-dose volume products for all product lines in which we compete. Our strength in this sector, combined with the importance of this segment to ipratropium bromide solution, make it the third most important target market.

Upon discharge, depending on disease severity, some of these patients will find themselves confined to Long Term Care facilities. This too becomes an excellent target for ipratropium. These facilities may be served by a centralized pharmacy, through hospital affiliations or mail order.

Market:	**Retail**
Supplied by:	DEY direct, RGDs, Wholesalers
Mkt. Potential vial volume 1996:	42 million

Retail includes chain pharmacies (warehousing and non-warehousing), and independent pharmacies.

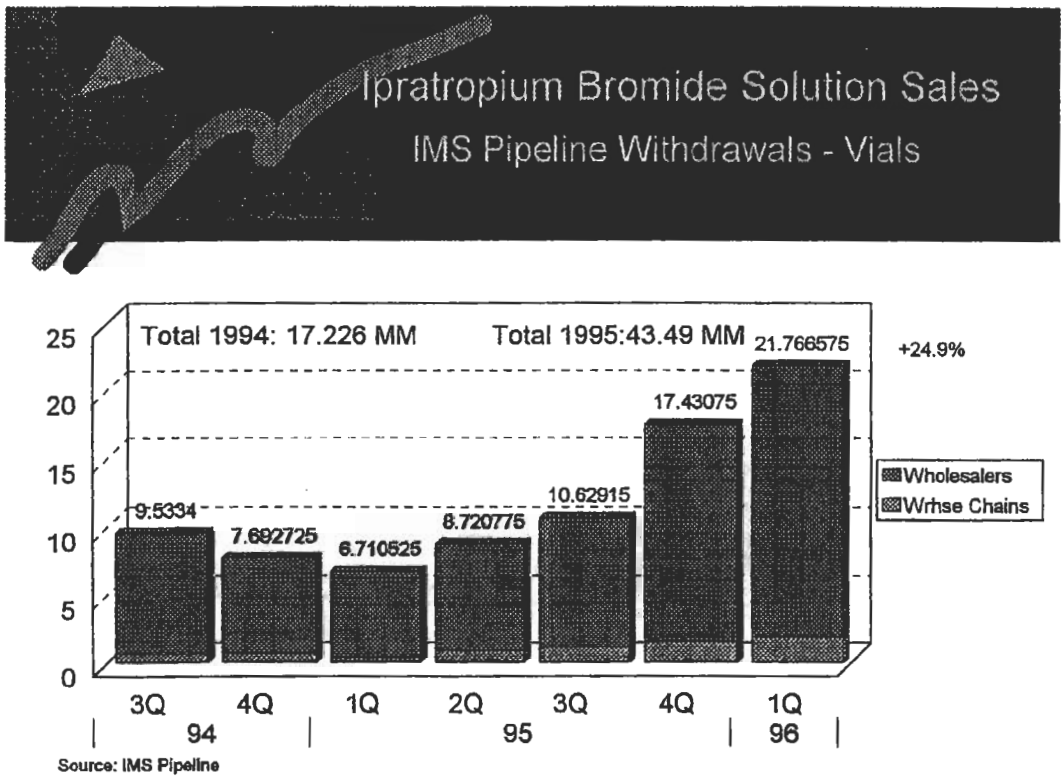
IMS sales figures illustrate that 50% of ipratropium bromide solution sales move through retail channels.

III. TARGET MARKETS (Continued)

Several issues make this an important sector for DEY to target:

1) COPD patients are on maintenance therapy with ipratropium bromide and will need to refill their prescriptions at a retail outlet.
2) DEY has a growing presence in the retail sector and neither Boehringer nor Roxane is particularly strong in this segment
3) In the retail sector, pharmacists like to minimize the number of manufacturers they must keep in touch with. The breadth of the DEY respiratory line gives DEY an advantage over Roxane.

Data on distribution channels illustrates that Boehringer has moved *Atrovent* solution almost exclusively through the wholesaler and that production volume is increasing, as 1Q96 shipments grew 25% in vial volume over previous quarter.



The dominance of BI and Roxane in wholesalers presents an opportunity for DEY with warehousing chains.

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DEY057-1988

IV. DEY SITUATION ANALYSIS

DEY Strengths:

- Packaging advantages
- Strength in hospital and home care markets
- Full line (primary interest: ipratropium, albuterol and metaproterenol for cocktailing; neither competitor has albuterol. Secondary interest: cromolyn, acetylcysteine and sodium chloride solutions)
- Respiratory focus
- Strong nebulizer share
- Multi-product deals: opportunities specific to COPD: along with ipratropium, albuterol (U-D, M-D, & MDI), and metaproterenol
- Aggressive contract utilization for managed care and GPOs
- DEY is known for high quality
- Customer-focused sales team

DEY Weaknesses:

- No recognition with PUD's, FP's, IM's
- Insufficient capacity for demand?
- Retail presence second to HHC and Hospital
- Smaller sales force

IV. DEY SITUATION ANALYSIS (continued)

Market Opportunities:

- Unfulfilled demand
  - Questionable relationship with wholesalers due to back order of solution
- Limited competition thus far
- Physicians may begin writing again with knowledge of second supplier
- NHLBI guidelines establish Ipratropium as 1st line therapy for COPD
- Chronic usage/high refill factor
- Projected growth of aging population
- Entrance into COPD market rounds out DEY as respiratory provider
- Packaging
  - Standard package size does not meet average Rx size (too small) - DEY provides a 60-pack
  - Compact package offers weight and size advantage to MO where DEY has a presence and competitors do not
- BI and Roxane only sell to distributors who are members of NWDA
- BI and Roxane distribute product almost exclusively through wholesalers

Market Threats:

- Not the 1st generic into market
- MD's frustrated by Atrovent B/O; not Rxing ipratropium as much
- Any new COPD therapies
- DEY has no ipratropium MDI
- Combivent received approvable letter
- Roxane entry into HHC with 3 year exclusive contract (possible realization of home care market potential)
- Other generic entrants
- Wholesaler relationship is not as strong as Roxane
  - DEY has a growing relationship with wholesalers compared to a company that is well entrenched with this channel

V. THE PRODUCT

DEY Ipratropium Bromide Inhalation Solution 0.02%:

Features	Benefits
ANDA approval:	Orange Book Listing: official rating recognition and improved reimbursement accordingly
AN rated:	**Confidence in effectiveness** **Easier reimbursement qualification**
Color-coded vial labels and cartons:	**Quick identification, matches carton** **Easy to read, leads to less errors**
Compact Cartons: • **smaller** • **2-sided** • **lighter (weighs less)**	**Shelf-space-friendly:** • **75% less shelf-space than competitors** • **can stack front or side** • **25's: 4.4 oz vs 5.8 oz (DEY is 24% less)** **(1st class postage= $1.24 vs $1.47)**
Multiple SKU's:	**60 pack = DEY exclusive; desired pkg size due to avg Rx** **25 pack = industry standard**
Familiar DEY Packaging: • ***TwistFlex*™ tops** • **DEY 5-strip style**	• **convenient, easy-to-open, and tamper evident** • **quick view/count of remaining doses**

- **Positioning Statement:**

DEY IPRATROPIUM is the "first choice" for first-line COPD nebulization therapy due to its preferred customer-focused packaging.[11]

Product Comparison Chart			
Feature:	**DEY**	**Roxane**	**BI**
Packaging	compact lighter DEY 5-strip style	large foil loose pack	large foil loose pack
Dating	18 month	18 month	18 month
UPC Barcode	Yes	Yes	Yes
Distribution centers	2	?	2
Distribution channels	All	limits distributors to those with NWDA license	limits distributors to those with NWDA license
ANDA approval	Yes	No	Yes
SKU's: 25's 60's	Yes Yes	Yes No	Yes No
Orange Book rating	AN	No	AN
Vial labeling	paper labels	translucent, embossed lettering	translucent, embossed lettering
Matching, color-coded vial label and carton	Yes	No	No
Price guarantees	Yes	Yes	Yes
Patient Education	Yes	No	Yes
Professional Education	Yes	No	Yes
All products for 1st & 2nd line COPD therapy (albuterol, metaproterenol, ipratropium)	Yes	No	No
Sales Force Size: -TAM's -ISR's -NAM's	 20 10 5	 75 ? 4	 400 ? 10

VI. CORPORATE GOALS AND OBJECTIVES

CORPORATE OBJECTIVES

Within first full year of launch, successfully launch Ipratropium Bromide to capture:

- **1996**:
  - 10% share of hospital/retail (7 MM vials)
  - 20% share of home care pharmacy (10 MM vials)

Total Vials
17 MM

- **1997**:
  - 36% share of hospital/retail (37 MM vials)
  - 76% share of home care pharmacy (38 MM vials)

Total Vials
75 MM

VII. MARKETING STRATEGIES AND TACTICS

STRATEGY

1. **Leverage our leadership position to garner market share:**

   — breadth of respiratory product line

   — quality of products

   — unit-dose dominant share

   — innovative packaging

TACTICS

1. Utilize multi-product deals in: Trade Promotions/Deals, and within our Contracts.

   - "Instant Cash" program with incentives to save more if customer buys multiple products. Choices are: ipratropium and Albuterol multidose and/or Albuterol unit-dose or ~~Metaproterenol~~
   - Primary objective is for ISR's to generate retail pull-through. Contract Group will mail addendums to contract customers and offer incentives (discounts) for multi-product purchases with predetermined performance criteria.
   - Offer an "InstaPay" type trade promotion via a direct mail co-op mailing after initial load in.
   - Offer a cromolyn/ipratropium free goods offer to select high-volume warehousing chain customers

VII. MARKETING STRATEGIES AND TACTICS

Tactics: (continued)

2. Incorporate a "Full Line Sell" into promotional pieces.

    - Draw from the DEY heritage and comprehensive respiratory care line DEY offers. DEY now has a product that is considered foundation therapy in COPD. Its intended use is chronic maintenance therapy. It is true that albuterol is frequently used in COPD, but it has a more broad range of use (at this time), and is not perceived as a COPD product. DEY now competes in both Asthma and COPD markets, with beta$_2$-andrenergic and anticholinergic bronchodilators, as well as mucolytics and sodium chloride solutions.
    - Incorporate ipratropium into comprehensive (full line) promotional pieces such an "all-product" Slim Jim and Product Listing.
    - Incorporate ipratropium convention graphics into existing show plans.

3. Develop "comparative" sell sheets and literature, that show and point out DEY packaging advantages.

    - Incorporate side by side visual comparisons of ipratropium and the competition in field training materials, selling resources, conversion pieces for pharmacists and/or patients.
    - Utilize comparison charts outlining features, benefits, and advantages of the DEY product.
    - Run an awareness campaign in key medical journals within targeted audiences, highlighting the DEY packaging advantages.

VII. MARKETING STRATEGIES AND TACTICS

STRATEGY

2A. Capitalize on our strengths in hospital, mail order and home health care where product is heavily used by attacking these segments most aggressively.

TACTICS

1. A *phased*-launch will begin following the regional launch meetings (depending on approval dates). Target accounts will be established and the sales force will begin to book orders. Phase I is as follows ***(see calendar in appendix)***:
   - **NAMs** will begin booking orders with home care accounts and mail order from their targeted lists.
   - **RSMs** will set up apptmts to meet with key GPOs (both retail and hospital), national wholesalers and larger RGDs
   - **TAMs** will set up apptmts to meet with regional GPOs

2. Establish volume pricing for HHC accounts based on albuterol unit-dose purchases.

3. HHC sample program staggered release based on purchase volumes.

4. Offer DEY Price Protection to accounts as-needed during presell and initial stocking period.

5. Contracts with renewal dates after October 1st will be handled in pricing committee.

6. Market share Cocktail Conversion Program: This program will be used to pull product from initial load-ins into the retail channel. The program will provide an opportunity to gain additional discounts if the customer purchases ipratropium and albuterol multidose.

VII. MARKETING STRATEGIES AND TACTICS

2B. Leverage the opportunity created by Boehringer Ingelheim and Roxane policy which excludes non-NWDA members and warehousing chains to gain a leadership position in retail market:

TACTICS

1. During the *phased*-launch, the second phase will focus on those accounts not well serviced by BI and/or Roxane. Target accounts will be established and the sales force will begin to book orders:
   - **NAMs** will begin booking orders with warehousing chains from their targeted lists.
   - **RSMs** will begin the contract process, will take orders from key GPOs, national wholesalers and RGDs, and will target chains from their target lists.
   - **TAMs** will set up appointments with regional wholesalers, RGDs and small chains. TAMs will also begin contract process for their accounts.
   - **ISRs** will support load-in efforts and solicit orders from their key retail accounts.

2. Establish pricing guidelines with "Price Protection" offered to accounts as-needed during the initial stocking period.

VII. MARKETING STRATEGIES AND TACTICS

Tactics: (continued)

3. Offer incentive programs to targeted Chain customers to gain distribution. Alternative deals under consideration are:

   - DEY PEY: Offer a "free goods" rebate to large warehousing retail chains based on performance objectives and market share achievement. The rebate will feature free cromolyn or ipratropium. Customers will be incentivized to select ipratropium to maximize their rebate potential.

   - As needed, create a custom program with volume discounts for warehousing chains to pull-through product and emphasize multi-product (full line) synergies and savings.

   - Mailing to chains highlighting DEY packaging advantages vs. competition. (See Direct Mail). Mailing to independent retailers highlighting.....

   - Market share Cocktail Conversion Program: This program will be used to pull product from initial load-ins into the retail channel. The program will provide an opportunity to gain additional discounts if the customer purchases ipratropium and albuterol multidose.

   - Instant Cash Program...

Do we need to address a Phase III: open launch to everyone else (regional wholesalers, independents, etc.) if no strategy attached to it?

VII. MARKETING STRATEGIES AND TACTICS

STRATEGY

3. Prioritize, target and convert purchasers of competitive products to DEY using customized promotional programs:

a. By channel

b. By product [Atrovent
generic

TACTICS

1. Consider offering the cromolyn/ipratropium free goods offer to other channels if it was successful with the warehousing chains.

2. Market share Cocktail Conversion Program: This program will be used to pull product from initial load-ins into the retail channel. The program will provide an opportunity to gain additional discounts if the customer purchases ipratropium and albuterol multidose. GPOs will be targeted as well as retail chains as they are able to demonstrate market share shifts.

3. Special terms and conditions (channel customized) to be determined.

4. Stocking incentives will be offered with channel specificity during the introductory offer period.

5. Pre-launch order forms for targeted accounts will be developed and ready for the phased roll-out.

VII. MARKETING STRATEGIES AND TACTICS

STRATEGY

4. Establish our position in COPD market by utilizing clinician and patient value-added programs.

TACTICS

1. Rep education: a comprehensive training module on COPD and ipratropium will be developed and mailed to the field in advance of the regional launch meetings. A test will be administered at the meeting.

2. COPD Patient Brochure: this will be developed to offer our representatives a valuable tool to gain increased access to care givers in COPD and to demonstrate the DEY commitment to COPD and respiratory care.

3. COPD Clinician Brochure: The current COPD and asthma pocket guide will be revised and will feature mention of DEY generics by category, thus supporting our full line strategy. The revised guide will incorporate an ipratropium ad, an image ad, and possibly a continuing education offer.

4. DEY Institute: Consideration will be given to establishing this as a credible sponsor dedicated to the advancement of COPD and asthma education in 1997. A modest budget would be set to cover limited contributions and the name would be used on collateral materials such our asthma and COPD patient education pieces.

VII. MARKETING STRATEGIES AND TACTICS

STRATEGY

5. Create awareness of DEY product among all purchasers and influencers.

TACTICS

1. Advertisements

   - Journal ads will feature our packaging advantages.
   - The media schedule will be a 6-8 month awareness campaign targeting major journals in key target markets.

2. Press Releases (PR)

   - Sent to key medical journal publishers.
   - Sent to key medical account executives.
   - Sent to key medical associations.

3. Announcement Mailings:

   Several announcement mailings are planned at launch to announce ipratropium:

   - Pricing databases: letters and information to be sent to First Data Bank, Medispan, Blue Book, etc.
   - 3rd party reimbursement: Medicaid letters and applicable forms to be sent.
   - Announcement letters with introductory terms sent to our direct accounts.
   - Announcement letters faxed to Field Fax list
   - Announcement letter to be sent to our indirect customers

   In addition, announcement flyers will be sent to pharmacists, respiratory therapists and targeted physicians (see Direct Mail).

VII. MARKETING STRATEGIES AND TACTICS

Tactics: (continued)

4. Convention Panels:

   Panels will be prepared for use at our approved trade shows and conventions. Consideration will be given to add key COPD conventions as resources permit.

   - 25 Duraflex for table-top and pop-up displays
   - 1 Duraflex for use in the 10' x 20' modular display

5. Sales Literature

   - Sell sheet with PI
   - Ad slick
   - New Item Fact Sheet
   - Journal ad reprints
   - RPh announcement flyer
   - RT announcement flyer
   - MD announcement flyer
   - Package Insert slicks
   - Pharmacy conversion piece (comparative)
   - Patient conversion piece (tear pad)
   - New comprehensive Slim Jim
   - All Product "Listing"
   - COPD patient education pamphlet in English and Spanish
   - COPD pocket guide (revised: 2nd edition)

VII. MARKETING STRATEGIES AND TACTICS

Tactics: (continued)

The month sequence listed for the following programs is a rolling sequence which will begin 4-6 weeks after the initial launch date. Months are currently based on an Oct. 1 approval date.

6. Direct Mail

RPh:

- November: Send independent pharmacists the announcement flyer via the Power-Pak co-op mailer.
- November: Send custom announcement mailer to Chain stores.

RT's:

- December: Custom Mailing of COPD Guide to all RT's
- December: Custom Mailing of pen with poster to all RT directors

MD's:

- January: Announcement flyer to targeted audiences including high-prescribing PUD's, IM's and FP's
- March: "Sample Offer" to targeted high-prescribers of *Atrovent*

6. Promotional giveaways for RT's and RPh's to be determined:
   - Car cigarette lighter plug: Stop COPD message.
   - Pen with scroll banner with cocktail dosing chart.
   - Blank phone Rx pads for pharmacy phone orders, with product ads interspersed within.
   - Key chain with lucite vial
   - Key chain with pen light

VII. MARKETING STRATEGIES AND TACTICS

STRATEGY

6. Set price and AWP to enhance sales while maximizing customer loyalty.

TACTICS

1. Develop price matrix comparing competitive listed prices.
2. Notify pricing databases and verify information is loaded into their systems.
3. Establish pricing guidelines for customer classes based upon volume and ability to move market share.
4. Prepare reimbursement worksheets.

VII. MARKETING STRATEGIES AND TACTICS

TACTICS (continued)

Direct Customer Terms:

- 5%, extra 60 day dating
- Offered to: Wholesalers, Chains and RGD's.
- Introductory period: 60 days post launch
- Big deal period: TBD

VII. MARKETING STRATEGIES AND TACTICS

TACTICS (continued)

Direct Customer Terms:

- 5%, extra 60 day dating
- Offered to: Wholesalers, Chains and RGD's.
- Introductory period: 60 days post launch
- Big deal period: TBD

VIII. LAUNCH PLAN IMPLEMENTATION

Ipratropium Launch Plan Activities Summary Chart																
Month	A	A	S	S	S	S	O	O	O	O	N	N	N	N	D	D
Week #	-6	-5	-4	-3	-2	-1	0	+1	+2	+3	+4	+5	+6	+7	+8	+9
Training Module Sent	x	x														
NAM's Presell/Sell		x	x	x	x	x	x	x	x							
RSM's Presell/Sell		x	x	x	x	x	x	x	x							
TAM's Presell/Sell				x	x	x										
ISR's Sell					x	x										
ISR's Retail Blitz				x	x	x	x	x	x	x						
Press release											x					
Trade letters								x		x	x					
Customer Fax								x		x	x					
Letter to Indirects												x				
Pricing databases							x									
Medicaid Mailing							x									
RPh Mailing to Independent												x	x	x	x	
Rph Mailing to Chains												x	x	x	x	
RT Mailing (COPD Guide)														x	x	x
RT Director Mailing (COPD Poster)															x	x
MD Announcement												January Mailing				
MD Sample Offer												March Mailing				
Journal Ads															x	x
DEY PEY				x	x	x		x	x	x	x					
Instant Cash Deal												x	x	x	x	

Ipratropium Pricing Guidelines:								
	DEY LABORATORIES				ROXANE		BOEHRINGER	
Customer Type:	25's	25's Per vial	60's	60's Per vial	25's	25's Per vial	25's	25's Per vial
AWP (% off brand)	44.10 -10%	1.76	105.60	1.76	44.06 -10.1%	1.76	49.00	1.96
WAC (% off *Atrovent* AWP)	25.50 -48%	1.02 -48%	60.90 -48.2%	1.015 -48.2%	26.44* -46%	1.06 -46%	40.80	1.63
Independent Retail Hospital List (% above WAC)	27.29 +7%	1.09 +7%	65.10 +7%	1.085 +7%	27.83	1.11		

* Net $21.90 (0.876/vial). Roxane offers 10% quarterly rebate and 8% royalty rebate [incl. Kinray]

Case sizes:
DEY 25's - 12 ctns.
DEY 60's - 12 ctns.
Roxane 25's - 48 ctns.
BI 25's - 48 ctns.

IX. APPENDIX

1. New *Atrovent* ad campaign
2. Older *Atrovent* ad campaign
3. Roxane ad
4. *Atrovent* cocktail chart
5. Roxane packaging

Exhibit 2

Exhibit 55

United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Boehringer Ingelheim Corp. et al.
Civil Action No. 07-10248-PBS

Exhibit to the July 24, 2009, Declaration of James J. Fauci
In Support of Plaintiff's Motion for Partial Summary Judgment and
In Opposition to the Roxane Defendants' Motion For Partial Summary Judgment

Coval, Paul J.

From: WATERER, JUDY ROXUS
Sent: Friday, October 02, 1998 11:52 AM
To: Grinton,Christopher SGEPH BIGDE
Cc: TUPA, EDWARD ROXUS
Subject: RE: BII GmbH enquiry

Ipratropium Bromide Pricing - Medispan 9/30/98

NDC#	Product Name	Supplier	AWP	WAC
00597-0080-62	Atrovent Solution for Inhalation	Boehringer Ingelheim	$ 55.62	$ 46.35
00054-8402-11	Ipratropium Bromide Solution for Inhalation	Roxane Laboratories	$ 44.06	$ 20.50
00054-8402-13	Ipratropium Bromide Solution for Inhalation	Roxane Laboratories	$ 52.87	$ 24.60
00054-8402-21	Ipratropium Bromide Solution for Inhalation	Roxane Laboratories	$ 105.74	$ 49.20
49502-0685-03	Ipratropium Bromide Solution for Inhalation	Dey Laboratories	$ 44.10	$ 20.25
49502-0685-33	Ipratropium Bromide Solution for Inhalation	Dey Laboratories	$ 52.80	$ 24.30
49502-0685-60	Ipratropium Bromide Solution for Inhalation	Dey Laboratories	$ 105.60	$ 48.60

As a reminder... These are published prices only. The AWP and WAC have little relation to actual net selling price *after chargebacks, discounts, rebates, etc. We are currently matching offers from Dey, in order to keep our business,* in the $13 range (for 25 vials). Customers purchase through bid prices utilizing the chargeback system and/or receive rebates, discounts and incentives in order to remain competative with Dey offerings. If you have further questions, please do not hesitate to let me know.

Kind Regards,

Judy Waterer
Manager, Program Development
Multisource Products
Phone: 614-276-4000 ext. 2480
Fax: 614-276-2470 or 614-276-3786

---Original Message---
From: Grinton,Christopher SGEPH BIGDE
Sent: Wednesday, September 30, 1998 11:11 AM
To: TUPA, EDWARD ROXUS
Cc: WATERER, JUDY ROXUS
Subject: RE: BII GmbH enquiry

Dear Ed

We would like to ascertain the ex-factory price(s) before rebates / discounts are applied.

Kind regards
Chris.

---Original Message---
From: TUPA, EDWARD ROXUS
Sent: Wednesday, September 30, 1998 1:40 PM
To: Grinton,Christopher SGEPH BIGDE
Cc: WATERER, JUDY ROXUS
Subject: RE: BII GmbH enquiry

We shall provide the information you request, but first we need to ask that you clarify your question. Do you want the manufacturers catalog price to wholesalers or the estimated actual selling price after all rebates and chargebacks? Or, do you want the estimated selling price by the wholesaler to the retailer? Once clarified, I will have Judy Waterer respond accordingly.

---Original Message---
From: Grinton,Christopher SGEPH BIGDE
Sent: Tuesday, September 29, 1998 1:17 PM
To: TUPA, EDWARD ROXUS
Cc: WATERER, JUDY ROXUS
Subject: BII GmbH enquiry

Dear Ed

ROX-6062

EXHIBIT
Waterer 51
DLS 10-25-01
PENGAD-Bayonne, N. J.

BII GmbH would greatly appreciate assistance with data needed by us to enter into a forecast model for BII's total respiratory business. The info. requested is as follows:

1. The (wholesale) price of ipratropium bromide unit dose vials ex Roxane.
2. The (wholesale) price of ipratropium bromide unit dose vials ex. Dey Labs.

The info. would be used confidentially within this model only, and for internal purposes only.

Hoping you can help

Kind regards

Christopher Grinton
Respiratory Product Manager
Corporate Division Marketing Medical Practices
Boehringer Ingelheim GmbH
Tel: 0049 (0)6132 77 2725
Fax: 0049 (0)6132 77 7452

ROX-6063